

Urgent Field Safety Notice – Update2

Notice Ref No:	SB-RPD_2013_06
Document Date:	08 May 2013
Type of Action	Field Corrective Action

PRODUCT AFFECTED:	CoaguChek XS
SYSTEM AFFECTED:	See above
MATERIAL NUMBERS:	04625412xxx [REDACTED]
SERIAL NO (IF APPLICABLE):	All serial numbers for CoaguChek XS
SUMMARY OF ISSUE:	ERROR 6 might require an urgent alternative INR measurement due to possibly high INR values
ACTION REQUIRED:	Under certain circumstances with ERROR 6, patients must contact their physician immediately
CONTACTS:	Technical Services: Country:

Reason for notice:

User information for your CoaguChek® XS instrument

Action required:

Dear Sir or Madam,

You have been using our CoaguChek® XS instrument for some time to regularly monitor your coagulation rate.

As you know, the CoaguChek® XS instrument measures your coagulation status up to an INR value of 8.0. It is known that, in very rare situations, INR values greater than 8.0 can occur – for example if the patient is undergoing antibiotic treatment or chemotherapy. The CoaguChek® XS instrument detects these very high values and displays the following two messages for your protection:

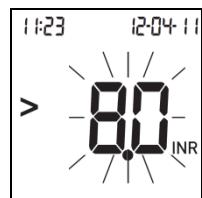


Fig. 1

or

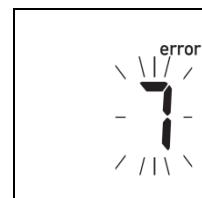


Fig. 2

In both cases, the user manual advises you to consult your doctor immediately.

In April 2013, we were made aware of a case in Norway in which antibiotic treatment resulted in a patient having an INR value greater than 10. However, the CoaguChek® XS instrument returned the following display:

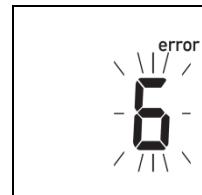


Fig. 3

The user manual tells you that an error has occurred in the measurement process. Although a very high INR value is practically excluded as a reason for this error message, we have decided – as a precautionary measure – to inform our CoaguChek® XS customers about the correct procedure to follow if an “error 6” message is displayed (Fig. 3).

What do I have to do if my CoaguChek® XS instrument displays “error 6”?

If this happens, the most likely cause is that an error has occurred in the measurement process. Please turn off the CoaguChek® XS instrument, remove the test strip and repeat the measurement with a new test strip. Make sure that you do not squeeze your finger while taking the blood and that you do not touch the test strip during the measurement – these are the two most frequent causes of an “error 6”. If you follow the correct procedure and “error 6” is displayed again, you should immediately consult your

doctor to have your coagulation status checked.

This is particularly important for you:

- The CoaguChek® XS instrument continues to perfectly measure your INR values – even if you are receiving antibiotic treatment or chemotherapy. The CoaguChek® XS instrument never produces incorrect values.
- 99.99% of cases in which an “error 6” is displayed result from an incorrect measurement process. Since the CoaguChek® XS instrument was introduced in 2006, the Norwegian case is the only case anywhere in the world in which an INR value greater than 10 has produced an “error 6”.

Our staff at the CoaguChek® Customer Service Center will be happy to answer any questions you may have regarding this letter. You can call the CoaguChek® Customer Service Center on (date/time) on (Telephone number).